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14. ABSTRACT
The overall goal of this study was to determine the levels of distress in women with a family history of ovarian cancer and to identify the mediating factors between risk of developing ovarian cancer and distress. One hundred and eleven women completed a mailed questionnaire about their subjective risk status, their knowledge of ovarian cancer and risk factors, uncertainty about ovarian cancer, levels of anxiety and depression, personality traits, and their interest in genetic testing. We received IRB approval in August 2004 and Human Subjects approval from the DoD on May 31, 2005. The grant was transferred from Beth Israel Medical Center in New York City to Thomas Jefferson University in Philadelphia on March 15, 2005. The age range was from 24 to 69 (M = 44, std. dev. = 10.41); 59% were married; 68% were Caucasian; 16% were Hispanic; 48% had a college or higher degree; and 59% worked full time. They reported a total of 73 relatives with ovarian cancer and 185 relatives with breast cancer. The mean of their levels of ovarian cancer anxiety (M = 12.43, std. dev. = 6.04) was in the middle range (0-24) and the mean of cancer worry (M = 5.13, std. dev.= .87) was at the lower end of the range (3-12). Data analyses are being completed and a manuscript prepared.

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Ovarian cancer risk, health behaviors, anxiety, depression

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INTRODUCTION

The overall goal of this study was to determine the levels of distress in women with a family history of ovarian cancer and to identify the mediating factors between risk of developing ovarian cancer and distress. One hundred and eleven women completed a mailed questionnaire about their subjective risk status, their knowledge of ovarian cancer and risk factors, uncertainty about ovarian cancer, levels of anxiety and depression, personality traits, and their interest in genetic testing. This study was a cross-sectional design. With the results generated by this study, we may be able to determine if women at risk for ovarian cancer need, or want, support in adjusting to their increased risk for cancer.

BODY

In the body of the report we will focus on the evidence that initially indicated the importance of this study, the model for this study and the measures used in the study.

Research on women with a family history of ovarian cancer

There is paucity in the literature regarding FDR's of ovarian cancer patients. The majority of studies have looked at women who are currently participating in an ovarian cancer screening program. Research studies have examined the psychological issues of participating in an Ovarian Cancer Registry or a Family Risk Assessment Program; the psychological impact of being screened for familial ovarian cancer; and the predictors of psychological distress among women at increased risk for ovarian cancer or women who are attending an ovarian cancer screening program. One study found that screening for ovarian cancer increased anxiety when a false-positive was found on ultrasonogoraphy and anxiety decreased in those who were true negatives. Another study found that CA-125 screening increased as both the number of relatives affected with ovarian cancer and cancer worries increased. A third study found that one-third of women attending a screening clinic for high risk women were above the cut-off point for depression and 16% were above the cut-off point for anxiety. Those who minimized their risk had no anxiety, and only 16% were clinically depressed. As the above research focuses on the psychological aspects of ovarian cancer screening, the broader psychological implications of dealing with the uncertainty of developing ovarian cancer have remained unexplored. With the exception of the one study, these studies have not looked at women who are FDR’s of index cases with ovarian

cancer. While the study of FDR's looked at personality style and coping as they affect psychological distress, it did not examine the uncertainty of screening, the uncertainty of genetic testing, nor the uncertainty of the outcomes of both screening for ovarian cancer and genetic testing.

Conceptual Framework: Uncertainty Model for Individuals at High Risk

The primary objective of this proposal is to look at the psychological consequences surrounding those women at increased risk for ovarian, augmented by the uncertainty surrounding screening for ovarian cancer and genetic testing for ovarian cancer. Within this context, a modification of the uncertainty in illness theory is the model that underlies the mediating processes between risk of ovarian cancer and levels of psychological distress. According to the theory, uncertainty is the "inability to determine the meaning of illness-related events". In this theory, uncertainty occurs when individuals do not have a cognitive schema for interpreting the illness-related event. In this proposal, the illness-related event is ovarian cancer risk. The theory further postulates that the outcome of uncertainty is affected by having a sense of mastery or control over the event. For this study, we postulate that women who can deal with uncertainty and feel that have some mastery or control over their ovarian cancer risk will be less psychologically distressed. Also, women who, in general, have a greater tolerance for ambiguity in their lives and see their future as more optimistic will be better equipped to deal with the uncertainty and be less psychologically distressed. The outcome of uncertainty is either feeling distressed or coping with distress through mastery and optimism. What is unknown about women at risk for ovarian cancer is the impact of; 1) knowledge, 2) health screening behaviors, and 3) other lifestyle behaviors, on their uncertainty about being at risk for ovarian cancer and levels of distress.

Measures

<u>Independent Variables</u>

Risk of Developing Ovarian Cancer was measured by a review of the family history of both ovarian and breast cancers as they are both related to BRCA1 and BRCA2 gene mutations.

Mediating Variables

Perceived Risk of developing ovarian cancer was assessed by having participants rate their chances of developing ovarian cancer during their lifetime on a scale from 0 (definitely will not get it) to 100 (definitely will get it).

Uncertainty about Ovarian Cancer Risk will be determined by the cognitive state of uncertainty as it relates to being at risk for ovarian cancer and has 20 items that determines the ambiguity, the lack of information, and complexity about being at risk for ovarian cancer (e.g., "I have a lot of questions without answers"). This measure is scored on a four point scale ranging from strongly disagree (1) to strongly agree (4). Some items are reverse-scored. Higher scores indicate greater uncertainty.

Personality Traits (Mastery, Tolerance, Optimism)

Mastery measures if an individual sees their life as being under their control or as a matter of luck and whether or not an individual is able to moderate difficult events in life, such as being at risk for ovarian cancer. The seven items are scored on a four point scale from strongly agree (1) to strongly disagree (4). Two items are reverse-scored.

Tolerance for Ambiguity is a seven-item scale that provides a sum score regarding the attitudes about decision-making and problem-solving in general (e.g., "The best part of working on a jigsaw puzzle is putting in that last piece"). The six point scale ranges from strongly disagree (1) to strongly agree (6).

Life Orientation Test (Optimism) assesses the general expectations of individuals as viewing life from a optimistic or pessimistic perspective. There are 12 items (four of which are filler items), rated on a five point Likert scale, ranging from "strongly disagree" (1) to "strongly agree" (5). Internal consistency was .74.

In order to assess participants' knowledge of risk factors for ovarian cancer, a face-valid eight-item questionnaire was created. Participants responded that the item was true, false, or they didn't know. A total risk factor knowledge score was computed for each participant by tabulating the number of correct responses. To assess knowledge of genetic testing, we used an eight-item measure regarding genetic testing. Participants responded that the item was true, false, or they

didn't know. A total genetic testing knowledge score was computed for each participant by tabulating the number of correct responses.

Sociodemographic Characteristics. A face-valid self-report form was used to assess participant's age, race, ethnicity, marital status, education, and employment status.

Outcome Variables

State Subscale of the Speilberger State-Trait Anxiety Scale (STAI). The state subscale of the Spielberger State-Trait Anxiety Scale is a widely used measure of state anxiety, which is relatively stable over time. There are 20 items, rated on a four point Likert scale, ranging from "never" to "always". Internal consistency was excellent as it ranged from .83 to .92.

Ovarian Cancer Anxiety (OCAS). This is a 21 item measure that was originally designed to determine breast cancer specific anxiety in women at risk for breast cancer. It is scored on a four point scale from not at all (0) to often (3).

Center for Epidemiologic Studies (CES-D). The CES-D is a 20 item scale used to assess current frequency of depressive symptoms with an emphasis on depressed affect or mood. The scores reflect each of six components: depressed mood, feelings of guilt and worthlessness, feelings of helplessness and hopelessness, psychomotor retardation, loss of appetite, and sleep disturbance. Respondents indicate how frequently they experienced the symptom within the past week, on a four point scale ranging from; "rarely or none of the time (less than 1 day)", "some or a little of the time (1–2 days)", occasionally or a moderate amount of time (3–4 days)", and "most or all of the time (5–7 days)."

Interest in Genetic Testing. Participants read a description adapted from previous studies of women at familial risk for breast cancer before rating their readiness to undergo genetic testing for ovarian cancer. After reading this statement, participants were instructed to identify what their plans would be if they were considering genetic testing. Response options were: 1) I plan to take the test as soon as possible (within the next 30 days); 2) I plan to take the test sometime in the near future (within the next 6 months); 3) I do not plan to take the test within the next 6 months.

Health Behaviors. In order to assess participants' health behaviors (including screening for breast and ovarian cancer), a series of face-valid questions have been devised from previous

scales for breast cancer. Specifically, women were asked if they are currently; 1) having transvaginal ultrasonography, CA-125, and pelvic examination, 2) undergoing mammography, clinical breast examination, and performing breast self-examination for breast cancer screening, and 3) engaging in other lifestyle changes, such as exercising, modifying their diet, and reducing alcohol and tobacco use. While screening for ovarian cancer is not currently recommended for women who are not gene mutation carriers, breast cancer screening and other healthy lifestyle behaviors are recommended. It is important to determine which of the above behaviors women are currently practicing, as they may be mediated by the predictor or controlling variables.

Work Accomplished as Related to Revised Statement of Work (approved) (*see Appendix A*)

Task 1 - All the items in Task 1 were accomplished. The PI, Dr. Kash moved from New York City to Philadelphia and assumed a position at Thomas Jefferson University in October 2003. The grant was transferred from Beth Israel Medical Center in New York City to Thomas Jefferson in March 2005. We received IRB approval at Thomas Jefferson University in August 2004 and approval from the DoD Human Subjects Review Committee on May 31, 2005.

Task 2 – We initialed recruited 14 women at Beth Israel Medical Center in New York City and began recruiting women in June 2005 at Thomas Jefferson University in Philadelphia. We accrued 97 women at Thomas Jefferson University and had a total of 111 participants at the end of the study in June 2007.

Task 3 – Data was collected and entered into a SPSS database. We have preliminary data in terms of demographics, family history of ovarian and breast cancers, and anxiety and worries about ovarian cancer. We continue to perform more detailed data analyses focused on the aims and hypotheses and are preparing a manuscript to be submitted.

Problems in Accomplishing Tasks as related to Statement of Work

Since October 2003, the PI, Dr. Kash, has been at Thomas Jefferson University in Philadelphia. It took from October 2003 until March of 2005 for Beth Israel Medical Center in New York City to transfer the grant. IRB approval from Thomas Jefferson University was received in August 2004. However it took an additional 10 months to receive approval from the DoD Human Subjects Approval Committee, which was received on May 31, 2005. At Thomas Jefferson

University, one of the two members of the Gynecological/Oncology team left Thomas Jefferson in July 2005, right when we received approval from the DoD to begin accrual. Despite this setback we have accrued a total of 111 women in a two-year period of time (through June 2007). With the advent of study participants being advised of their HIPAA rights and the use of PHI in research, as well as the researchers' inability to contact potential participants, fewer individuals are reached and are willing to participate in research studies. Preliminary analyses have been conducted and demographic information is reported in this report. The data interactions are still being conducted and will be submitted as a manuscript from this study.

In summary, Tasks 1 and 2 and most of Task 3 have been completed. None of the goals or objectives of the study have changed. The conceptual model for this study (*see Appendix B*) is the same as in the original proposal. We are moving forward and are actively completing the data analyses for this study.

RESULTS

We recruited a total of 111 women into the study, which was labor intensive as we moved the study from one institution to another and dealt with the rules of PHI and HIPAA. Since we were unable to contact women to participate in the study, we distributed flyers in the Gynecological-Oncology suite at Thomas Jefferson, in Curves Fitness Centers (for women only) and ovarian cancer events in and around Philadelphia. While research shows that speaking one-on-one with a potential research participant is the best way to recruit for studies, we had to rely on flyers being placed in key areas in order to have women contact us for the study. We will report on the demographics, family history and ovarian cancer anxiety and worries in this report. We are still conducting data analyses and preparing a manuscript for submission.

Demographics (Appendix B, Table 1)

As shown in Table 1, the demographic variables are described below and the highest percentages are bolded in the table. The mean age for the participants was 44 with a standard deviation of 10.41. The age range was from 24 to 69 years old. Most of the women were married or living as married (58.6%) or single or never married (30.6%). For the racial composition, 68.5% identified as White and 20.7% identified as African American. We included ethnicity in a separate category

in terms of Hispanic or non-Hispanic as is currently being done at the National Institutes of Health (NIH). Sixteen percent identified themselves as being Hispanic while 82.9% did not. Some Hispanic women identified themselves as White while others identified themselves as African American or other. For education, the large representation was some college (28.8%) and college (27%) with 52% having had at least some college. A significant number of women are employed full time (58.6%) and part time (12.6%), while 15.3% identified themselves as being homemakers.

Family History of Participants (Appendix B, Table 2)

Women were recruited into the study if they had a family history of ovarian cancer in a first degree relative. However, looking at the family history there are only 58 women with a first degree relative with breast cancer and 15 women with a second degree relative with ovarian cancer, for a total of 73 women with ovarian cancer who were relatives of the participants. There were a total of 184 first and second degree relatives with breast cancer, indicating that some women had more than one relative (first or second degree) with breast cancer. Further exploration is needed for why there were more relatives with breast cancer than ovarian cancer. It is possible that since the BRCA1 and BRCA2 gene mutations confer a higher risk for both breast and ovarian cancer that some women thought if they had a relative (or two) with breast cancer than they were at increased risk for ovarian cancer. There were questions asked about other relatives (e.g., second degree cousins) which have not been included in the information above. We will investigate if there are any other relatives with ovarian or breast cancer in the family lineage.

Ovarian Cancer Anxiety and Ovarian Cancer Worries (Appendix B, Table 3)

We have looked at the anxiety and worries levels about ovarian cancer as a prelude to analyzing the data in order to determine if there is a relationship between these anxieties and worries and more general anxiety and depression as well as looking at possible mediators of this relationship. The ovarian cancer anxiety scale had a range of 0 to 24 (full range of scores) with a mean of 12.43 and a standard deviation of 6.04. There were several modes: 7, 11, and 15. It appears that this scale is evenly distributed. The ovarian cancer worries scale had a range of 3 to 9 (out of a possible 3 to 12) with a mean of 5.13 and a standard deviation of 1.87. The mode was 3. There

were three questions that made up this scale which revolved around how often women thought about their own chances of developing ovarian cancer, how often their thoughts about ovarian cancer affected their mood, and how often their thoughts about ovarian cancer affected their ability to perform their daily activities. It appears that the lower scores on this three-item scale were related to how their thoughts affected their daily activities. While thinking often about their chances of developing ovarian cancer may occur more often than not, these thoughts do not impact their mood or performance of daily activities very much. As we continue the data analyses we will be able to determine how family history and other variables impact their general anxiety and depression scores as well as ovarian cancer specific anxiety and worries.

KEY RESEARCH ACCOMPLISHMENTS

- Accrued 111 women into the study
- All data has been entered and cleaned
- Preliminary data analyses has begun with more substantive analyses to be completed by the end of August 2008
- Manuscript background has begun with new literature review

REPORTABLE OUTCOMES

There was an abstract presented about the conceptual framework which was submitted with our previous report. It is attached again in Appendix D. In addition we reported on the design, the measures, and the initial data collection in an abstract in 2006 at the World Congress of Psycho-Oncology. It is attached in Appendix E.

CONCLUSIONS

We received approval of our protocol by the IRB in August 2004 and approval from the DoD Human Subjects Committee in May 2005. In March of 2005 the grant was officially transferred from Beth Israel Medical Center in New York City to Thomas Jefferson University in Philadelphia. We have accrued 97 women in a two-year period of time in addition to the 14 participants at Beth Israel Medical Center in New York City. While this number is short of our goal of 180 women participating in the study, we are assured that the data analyses will have sufficient power to be conducted. We will be able to conduct data analyses on the main aims and hypotheses of this study.

The demographic variables, the family history, and preliminary report of two of our outcome measures are very interesting and we will further examine the relationship not only between the outcome measures but also how family history and perception of risk impacts interest in genetic testing. The data analyses are moving forward and we anticipate completion at the end of August 2008. At that time we will submit a manuscript for publication and send a copy of any publications to the U.S. Army Medical Research and Material Command.

APPENDIX A

REVISED
STATEMENT OF WORK

LEVELS OF DISTRESS IN WOMEN AT RISK FOR OVARIAN CANCER

START: May 31, 2005
Items in bold are changes from the initial SOW.

Task 1. - Preparation of materials, data program, and training of staff Completed

a. Measures are finalized.
b. Questionnaires copies.
c. Scripts for contacting potential participants are finalized.
d. Research Coordinator trained in recruitment procedures.
e. Codebook will be finalized.
f. Program for data entry will be written.

Task 2. - Recruitment of participants - Completed

a. Index cases with diagnosed ovarian cancer will be sent a letter describing the study by the physicians in the **Gynecologic Oncology practices at Thomas Jefferson University**. The researchers will contact the index cases, if they do not opt out, within two weeks and provide more information about the study. Index cases will pass this information on to their sisters and daughters (FDRs) and have them contact the researchers directly if they are interested in participating. In addition, **flyers will be placed in the Obstetrics and Gynecology practices at Thomas Jefferson University, at the Sandy Rollman Ovarian Cancer Foundation programs, and at the Curves Fitness Center (for women only), advertising the study for women with a family history of ovarian cancer.**
b. Contacted by unaffected female FDRs (total N=111).
c. Researchers speak with potential participants using telephone script to assess eligibility and determine interest in participation.
d. Study packet mailed to those interested in participation.
e. Participants returned the informed consent and study questionnaire by mail.

Task 3. - Data entry and analyses - Partially Completed

a. Data entry is begun in month 13. (Completed)
b. Preliminary data analyses are begun in month 21. (Completed)
c. Final analyses are completed in month 23. (In Progress)

APPENDIX B

Table 1. Demographics of study participants (N=111)

Variable		
Age	Mean=44 Std. Dev.=10.41 (range from 24-69)	
Marital Status		Number (%)
	Single or never married	**34 (30.6)**
	Married or living as married	**65 (58.6)**
	Separated or divorced	9 (8.1)
	Widowed	3 (2.7)
Racial		
	White	**76 (68.5)**
	African American	**23 (20.7)**
	Asian	7 (6.3)
	Native American	1 (.9)
	Other	4 (3.6)
Ethnic		
	Hispanic	**18 (16.2)**
	Non-Hispanic	**92 (82.9)**
	Other	1 (.9)
Grade		
	Less than high school	1 (.9)
	High school or GED	**18 (16.2)**
	Technical/Vocational	7 (6.3)
	Some college	**32 (28.8)**
	College	**30 (27.0)**
	Graduate school	**16 (14.4)**
	Post-graduate school	7 (6.3)
Employment		
	Full time	**65 (58.6)**
	Part time	**14 (12.6)**
	Retired	7 (6.3)
	Homemaker	**17 (15.3)**
	Disabled	2 (1.8)
	Student	2 (1.8)
	Unemployed	4 (3.6)

Table 2. Family History of Participants (N=111)

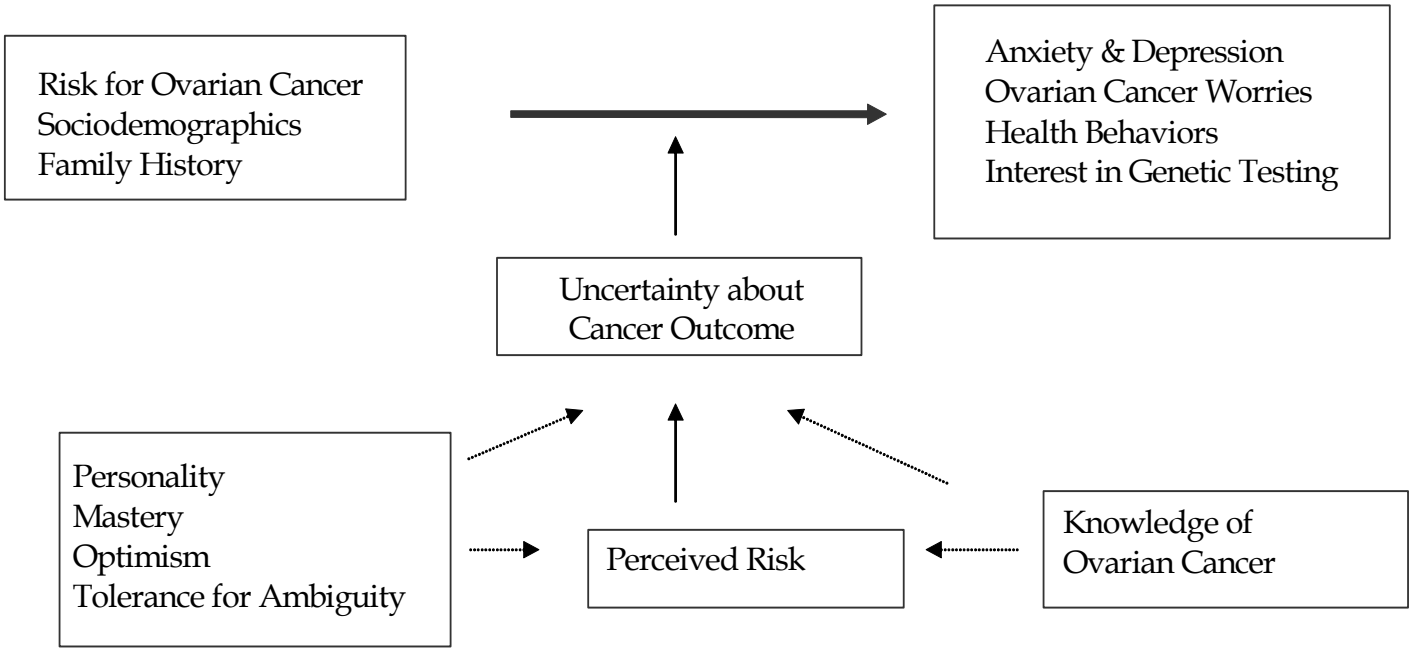
	Type of Cancer	
Relative	**Ovarian (N)**	**Breast (N)**
Mother	41	76
Sister	17	47
Grandmother (paternal or maternal)	7	36
Aunt (paternal or maternal)	8	25
TOTAL	73	184

Table 3. Cancer Worries Scale (range 3 – 9)

	Thought about chances	Affected your mood	Affected your daily activities
Mean	2.35	1.83	1.47
Std. Dev.	1.05	.725	.569
Media	2	2	1
Mode	2	2	1
Range	1-4	1-3	1-3

APPENDIX C

CONCEPTUAL FRAMEWORK



APPENDIX D

Levels of Distress in Women with a Family History of Ovarian Cancer

Kathryn M. Kash, Ph.D. & Mary Kay Dabney, M.S.
Beth Israel Medical Center, New York, NY, USA

Presented at the 7th International Meeting on Psychosocial Aspects of Genetic Testing for Hereditary Cancer – Marseilles, France – March 2001

Introduction. There is evidence to suggest that women with a family history of ovarian cancer are at higher than average risk for the disease and a small percentage are gene mutation carriers. To date, there have been no systematic studies of women who are at this increased risk because of their family history and the relationship between actual risk and levels of emotional distress as mediated by personality factors, perception of risk, and knowledge of ovarian cancer risk factors. Our proposal will envelope a much broader scope than previous work by looking at the distress associated with increased risk for ovarian cancer in FDR's (first-degree relatives) of index cases, rather than women attending screening clinics, while examining the predictor variables of such distress. We are particularly interested in how specific personality traits mediate level of distress. . For example, one would expect that women who have a sense of mastery and optimism and better tolerance for ambiguity, would be able to handle the uncertainty regarding being at increased risk for ovarian cancer and thus feel less distressed. In addition, we plan to look at the FDR's knowledge of genetic testing for ovarian cancer, perception of being a gene mutation carrier, and interest in genetic testing (as it relates to ovarian cancer). Perhaps the most serious limitation of genetic testing is that state-of-the-art diagnostics do not match test information. To receive positive genetic test results when there is no adequate screening is tragic.

Goals of Study. The overall goal of this study is to determine the levels of distress in women with a family history of ovarian cancer and to identify the mediating factors between risk of developing ovarian cancer and distress. With the results generated by this study, specific interventions can be designed and tested to improve adjustment of women at high risk for ovarian cancer.

Research Design. The proposed study will use 180 first-degree relatives (FDR) of women diagnosed with ovarian cancer in a cross-sectional design. Information the ovarian cancer index case provides will be used to identify maternal relatives (mothers, sisters, or daughters). Women will be queried about their objective and subjective risk status, their knowledge of ovarian cancer and risk factors, their uncertainty about ovarian cancer, levels of anxiety and depression, their personality traits of mastery, tolerance for ambiguity, and optimism, and their interest in genetic testing.

APPENDIX E

Levels of Distress in Women with a Family History of Ovarian Cancer

Kathryn M. Kash, Ph.D. Thomas Jefferson University, Philadelphia, PA USA

Poster Presentation at the World Congress of Psycho-Oncology in October 2006

Introduction There is evidence to suggest that women with a family history of ovarian cancer are at higher than average risk for the disease and a small percentage are gene mutation carriers. To date, there have been no systematic studies of women who are at this increased risk because of their family history and the relationship between actual risk and levels of emotional distress as mediated by personality factors, perception of risk, and knowledge of ovarian cancer risk factors. Our proposal will envelope a much broader scope than previous work by looking at the distress associated with increased risk for ovarian cancer in FDR's (first-degree relatives) of index cases, rather than women attending screening clinics, while examining the predictor variables of such distress. We are particularly interested in how specific personality traits mediate level of distress. . For example, one would expect that women who have a sense of mastery and optimism and better tolerance for ambiguity, would be able to handle the uncertainty regarding being at increased risk for ovarian cancer and thus feel less distressed. In addition, we plan to look at the FDR's knowledge of genetic testing for ovarian cancer, perception of being a gene mutation carrier, and interest in genetic testing (as it relates to ovarian cancer). Perhaps the most serious limitation of genetic testing is that state-of-the-art diagnostics do not match test information. To receive positive genetic test results when there is no adequate screening is tragic.

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Results To date we have collected data on 32 women. Their mean age is 57 (range 48-64); the majority are married (42%); education ranges from high school to graduate degree; and most had a sister with ovarian cancer. Further results information will be presented at the congress as we anticipate that 80 more women will have completed the questionnaire by the time of the meeting in October.